Manipulation under Anesthesia

Policy # 00313
Original Effective Date: 09/14/2011
Current Effective Date: 04/19/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers spinal manipulation (and manipulation of other joints, e.g., hip joint, performed during the procedure) with the patient under anesthesia, spinal manipulation under joint anesthesia, and spinal manipulation after epidural anesthesia and corticosteroid injection for treatment of chronic spinal (cranial, cervical, thoracic, lumbar) pain and chronic sacroiliac and pelvic pain to be investigational.*

Based on review of available data, the Company considers spinal manipulation and manipulation of other joints under anesthesia involving serial treatment sessions to be investigational.*

Based on review of available data, the Company considers manipulation under anesthesia (MUA) involving multiple body joints for treatment of chronic pain to be investigational.*

Note: This policy does not address manipulation under anesthesia for fractures, completely dislocated joints, adhesive capsulitis (e.g., frozen shoulder), and/or fibrosis of a joint that may occur following total joint replacement.

Background/Overview
Manipulation under anesthesia consists of a series of mobilization, stretching, and traction procedures performed while the patient is sedated (usually with general anesthesia or moderate sedation).

Manipulation is intended to break up fibrous and scar tissue to relieve pain and improve range of motion. Anesthesia or sedation is used to reduce pain, spasm, and reflex muscle guarding that may interfere with the delivery of therapies and to allow the therapist to break up joint and soft-tissue adhesions with less force than would be required to overcome patient resistance or apprehension. Manipulation under anesthesia is generally performed with an anesthesiologist in attendance. Manipulation under anesthesia is an accepted treatment for isolated joint conditions, such as arthrofibrosis of the knee and adhesive capsulitis. It is also used to treat (reduce) fractures (e.g., vertebral, long bones) and dislocations.

Manipulation under anesthesia has been proposed as a treatment modality for acute and chronic pain conditions, particularly of the spinal region, when standard care, including manipulation, and other conservative measures have been unsuccessful. Manipulation under anesthesia of the spine has been used in various forms since the 1930s. Complications from general anesthesia and forceful long-lever, high-amplitude nonspecific manipulation procedures resulted in decreased use of the procedure in favor of other therapies. Manipulation under anesthesia was modified and revived in the 1990s. This revival is attributed
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to increased interest in spinal manipulative therapy and the advent of safer, shorter-acting anesthesia agents used for conscious sedation.

Manipulation under anesthesia of the spine is described as follows: after sedation is achieved, a series of mobilization, stretching, and traction procedures to the spine and lower extremities is performed and may include passive stretching of the gluteal and hamstring muscles with straight-leg raise, hip capsule stretching and mobilization, lumbosacral traction, and stretching of the lateral abdominal and paraspinous muscles. After the stretching and traction procedures, spinal manipulative therapy (SMT) is delivered with high-velocity, short-amplitude thrust applied to a spinous process by hand while the upper torso and lower extremities are stabilized. SMT may also be applied to the thoracolumbar or cervical area if considered necessary to address the low back pain.

Manipulation under anesthesia takes 15 to 20 minutes, and after recovery from anesthesia, the patient is discharged with instructions to remain active and use heat or ice for short-term analgesic control. Some practitioners recommend performing the procedure on 3 or more consecutive days for best results. Care after MUA may include 4 to 8 weeks of active rehabilitation with manual therapy, including SMT and other modalities. Manipulation has also been performed after injection of local anesthetic into lumbar zygopophyseal (facet) and/or sacroiliac joints under fluoroscopic guidance (manipulation under joint anesthesia/analgesia) and after epidural injection of corticosteroid and local anesthetic (manipulation postepidural injection). Spinal manipulation under anesthesia has also been combined with other joint manipulation during multiple sessions. Together, these therapies may be referred to as medicine-assisted manipulation.

Food and Drug Administration (FDA) or Other Governmental Regulatory Approval
Manipulative procedures are not subject to regulation by the FDA.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD).

Rationale/Source
The most recent policy update with literature review was performed through July 11, 2016.

Assessment of efficacy for therapeutic interventions involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Randomized, placebo-controlled trials are considered particularly important when assessing treatment of low back pain, to control not only for the expected placebo effect but to also control for the variable natural history of low back and pelvic pain, which may resolve with conservative treatment alone. Dagenais et al, in a 2008 comprehensive review of the history of MUA or medicine-assisted manipulation (MAM) and the published experimental literature, noted that there is no research to confirm theories about a mechanism of action for these procedures and that the only RCT identified was published in 1971 when the techniques for spinal manipulation differed from those used presently.
No high-quality RCTs have been identified. A 2013 comprehensive review of the literature described studies by Kohlbeck et al (2005) and Palmieri and Smoyak (2002, described next) as being the best evidence available for MAM/MUA of the spine. Kohlbeck et al reported a nonrandomized comparative study that included 68 patients with chronic low back pain. All patients received an initial 4- to 6-week trial of SMT, after which 42 patients received supplemental intervention with MUA and 26 continued with SMT. Low back pain and disability measures favored the MUA group over the SMT-only group at 3 months (adjusted mean difference on a 100-point scale, 4.4 points; 95% confidence interval [CI], -2.2 to 11.0). This difference attenuated at 1 year (adjusted mean difference, 0.3 points; 95% CI, -8.6 to 9.2). The relative odds of experiencing a 10-point improvement in pain and disability favored the MUA group at 3 months (odds ratio [OR], 4.1; 95% CI, 1.3 to 13.6) and at 1 year (OR=1.9; 95% CI, 0.6 to 6.5).

Palmieri and Smoyak evaluated the efficacy of using self-reported questionnaires to study MUA using a convenience sample of 87 subjects in 2 ambulatory surgery centers and 2 chiropractic clinics. Thirty-eight patients with low back pain received MUA and 49 received traditional chiropractic treatment. A numeric pain scale and Roland-Morris Disability Questionnaire (RMDQ) were administered at baseline, after the procedure, and 4 weeks later. Average pain scale scores in the MUA group decreased by 50% versus 26% in the traditional treatment group; RMDQ scores decreased by 51% and 38%, respectively. The authors concluded that the study supports the need for large-scale studies on MUA and that the assessments are easily administered and dependable. Although the authors concluded that the study supports the need for large-scale studies on MUA and that the assessments are easily administered and dependable, no large-scale studies comparing MUA to traditional chiropractic treatment have been identified.

In 2014, Peterson et al reported a prospective study of 30 patients with chronic pain (17 low back, 13 neck) who underwent a single MUA session with follow-up at 2 and 4 weeks. The primary outcome measure was the Patient’s Global Impression of Change (PGIC). At 2 weeks, 52% of the patients reported clinically relevant improvement (better or much better) with 45.5% improved at 4 weeks. There was a statistically significant reduction in numeric rating scale (NRS) scores at 4 weeks (p=0.01) from a mean score of 4.0 at 1 day before MUA to 3.5 at 2 weeks post-MUA. Bournemouth Questionnaire (BQ) scores improved from 24.17 to 20.38 at 2 (p=0.008) and 19.45 at 4 weeks (p=0.001). This study lacked a sham group to control for a potential placebo effect. In addition, the clinical significance of improved NRS and BQ scores is unclear.

West et al reported on a series of 177 patients with pain arising from the cranial, cervical, thoracic, and lumbar spine, as well as the sacroiliac and pelvic regions who had failed conservative and surgical treatment. Patients underwent three sequential manipulations with intravenous (IV) sedation followed by 4–6 weeks of spinal manipulation and therapeutic modalities; all had six months of follow-up. On average, visual analogue scale (VAS) ratings improved by 62% in patients with cervical pain and 60% in patients with lumbar pain. Dougherty et al. retrospectively reviewed outcomes of 20 cervical and 60 lumbar radiculopathy patients who underwent MUESI. After epidural injection of lidocaine (guided fluoroscopically or with computed tomography), methylprednisolone acetate flexion distraction mobilization and then high-velocity, low-amplitude spinal manipulation was delivered to the affected spinal regions. Outcome criteria were empirically defined as significant improvement, temporary improvement, or no change. Among lumbar spine patients, 22 (37%) noted significant improvement, 25 (42%) reported temporary improvement, and 13 (22%)
no change. Patients receiving cervical epidural injection reported the following: 10 (50%) significant improvement, 6 (30%) temporary relief, and 4 (20%), no change.

The only study of manipulation under joint anesthesia/analgesia (MUJA) found had 4 subjects. Later, Michaelsen noted in a 2000 article that MUJA should be viewed with "guarded optimism because its success is based solely on anecdotal experience."

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in July 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 physician specialty societies and 4 academic medical centers while this policy was under review in 2009. Input from the 7 reviewers agreed that MUA for chronic spinal and pelvic pain is investigational.

Summary
For individuals who have chronic spinal, sacroiliac, or pelvic pain who receive MUA, the evidence includes case series and nonrandomized comparative studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Scientific evidence on spinal MUA, spinal manipulation with joint anesthesia, and spinal manipulation after epidural anesthesia and corticosteroid injection is very limited. No randomized controlled trials have been identified. Evidence on the efficacy of MUA over several sessions or for multiple joints is also lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

References

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09/01/2011 Medical Policy Committee review
09/14/2011 Medical Policy Implementation Committee approval. New policy.
12/08/2011 Medical Policy Committee review
12/06/2012 Medical Policy Committee review
12/19/2012 Medical Policy Implementation Committee approval. No change to coverage.
12/12/2013 Medical Policy Committee review
12/18/2013 Medical Policy Implementation Committee approval. No change to coverage.
04/02/2015 Medical Policy Committee review
04/20/2015 Medical Policy Implementation Committee approval. No change to coverage.
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed
04/07/2016 Medical Policy Committee review
04/20/2016 Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
04/06/2017 Medical Policy Committee review
04/19/2017 Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 4/2018

Coding
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Codes used to identify services associated with this policy may include (but may not be limited to) the following:
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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

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